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purposes of this paragraph (a)(9), an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.

(iii) For purposes of this paragraph (a)(9), 0.05 microcurie of americium-241 is considered an exempt quantity under § 30.71, Schedule B.

(10) [Reserved]

(b) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in paragraph (a) of this section, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to § 32.14 of this chapter, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

[31 FR 5316, Apr. 2, 1966]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 30.15, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 30.18 Exempt quantities.

(a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

(b) Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person

possesses, uses, transfers, or owns byproduct material.

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

(e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007]

§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20 and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured,

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processed, produced, or initially transferred in accordance with a specific license issued pursuant to §32.22 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to §32.22 of this chapter, which license states that the product may be transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.

(c) The exemption in paragraph (a) of this section does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

[34 FR 9026, June 6, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

§30.20 Gas and aerosol detectors containing byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, and 30 through 36, and 39 of this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under §32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to §32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to §32.26 of this chapter, which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.

[34 FR 6653, Apr. 18, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007]

§30.21 Radioactive drug: Capsules containing carbon-14 urea for “in vivo” diagnostic use for humans.

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in this part and part 35 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for “in vivo” diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to part 35 of this chapter.

(c) Any person who desires to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to §32.21 of this chapter.

(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

[62 FR 63640, Dec. 2, 1997]

LICENSES

§30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific.